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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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SWANSON & BRATSCHUN L.L.C.			RINES, ROBERT D	
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SUITE 330			PAPER NUMBER	
HIGHLANDS RANCH, CO 80129			3626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/910,463	<b>Applicant(s)</b> HUYN ET AL.	
	<b>Examiner</b> Robert D. Rines	<b>Art Unit</b> 3626	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 July 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/10/01, 10/9/01...</u> | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

*Notice to Applicant*

[1] This communication is in response to the patent application filed 20 July 2001. It is noted that this application benefits from Provisional Patent Application Serial No. 60/220,135 filed 21 July 2000 and Provisional Patent Application Serial No. 60/220,204 filed 18 August 2000. The IDS statements filed 10 September 2001, 9 October 2001, 7 December 2001, 3 December 2004, 31 January 2005, and 10 February 2005 have been entered and considered.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[2] Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

[A] Claim 26 recites the limitation "said form linking condition" in line 3 of claim 26. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

[3] Claims 1-5, 20, 22, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Haessler et al., (United States Patent #4,130,881).

[A] As per claim 1, Haessler et al., discloses a computer-implemented method for obtaining clinical data (Haessler et al.; col. 1, lines 14-15 and col. 2, lines 65-68 and col. 3, lines 1-10 and Fig. 1), comprising: obtaining a plurality of medical questions and at least one question linking condition from a database (Haessler et al.; col. 1, lines 46-55 and col. 2, lines 18-23); presenting at least one of said medical questions to a user (Haessler et al.; col. 2, lines 18-23); receiving response data from said user (Haessler et al.; col. 3, lines 13-18); and in dependence on said response data and said question linking condition, determining which additional of said medical questions to present to said user (Haessler et al.; col. 3, lines 13-18 and col. 4, lines 15-20).

[B] As per claim 2, Haessler et al., discloses wherein each of said medical questions is associated with a corresponding question linking condition (Haessler et al.; col. 2, lines 18-24),

and wherein said determining step comprises evaluating each of said corresponding question linking conditions in dependence on said response data (Haessler et al.; col. 2, lines 24-35).

[C] As per claim 3, Haessler et al., discloses further comprising presenting to said user medical questions whose corresponding question linking conditions evaluate to true (Haessler et al.; col. 5, lines 29-38).

[D] As per claim 4, Haessler et al., discloses wherein said medical questions comprise higher-level questions and lower-level questions (Haessler et al.; col. 4, lines 15-31).

[E] As per claim 5, The method of claim 4, wherein said presented questions are higher-level questions (Haessler et al.; col. 4, lines 15-20), and said method further comprises presenting at least one of said lower-level questions to said user if said response data represent at least one positive response (Haessler et al.; col. col. 4, lines 20-32).

[F] As per claim 20, Haessler et al., discloses wherein said presenting step comprises presenting information selected from the group consisting of graphical, textual, and audio information to said user (Haessler et al.; col. 3, lines 1-28).

[G] As per claim 22, Haessler et al. discloses further comprising evaluating the consistency of said response data (Haessler et al.; col. 4, lines 40-60).

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[H] As per claim 23, Haessler et al. discloses further comprising presenting a summary of said response data (Haessler et al.; col. 1, lines 14-18).

[4] Claims 29 and 30 rejected under 35 U.S.C. 102(e) as being anticipated by Iliff (United States Patent #6,569,093).

[A] As per claim 29, Iliff teaches a program storage device accessible by a processor, tangibly embodying a program of instructions executable by said processor to perform method steps for obtaining clinical data (Iliff; col. 30, lines 10-15), said method steps comprising: obtaining a plurality of medical questions and at least one question linking condition from a database (Iliff; col. 30, lines 25-38); presenting at least one of said medical questions to a user (Iliff; col. 31, lines 3-7); receiving response data from said user (Iliff; col. 2, lines 15-32); and in dependence on said response data and said question linking condition, determining which additional of said medical questions to present to said user (Iliff; col. 2, lines 15-32).

[B] As per claim 30, Iliff teaches a clinical questionnaire system comprising: a database for storing a plurality of questionnaire objects comprising clinical questions and question presentation conditions (Iliff; col. 14, lines 8-11 and Abstract); a web server in communication with said database (Iliff; col. 55, lines 52-55, col. 51, lines 19-21, and col. 30, lines 30-38); and a web browser in communication with said web server (Iliff; col. 55, lines 52-55 and col. 30, lines 30-38), said web browser for presenting selected ones of said clinical questions to a user and receiving response data (Iliff; col. 51, lines 19-21), wherein said selected clinical questions are

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selected in dependence on said question presentation conditions and on said response data (Iliff; col. 2, lines 15-32).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

[5] Claims 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iliff.

[A] As per claim 24, Iliff teaches a computer-implemented method for obtaining clinical data, comprising: obtaining a plurality of forms and at least one form linking condition from a database (Iliff; col. 12, lines 35-38 and col. 47 lines 57-61 and col. 2 lines 15-32), each form comprising at least one medical question (Iliff; col. 12, lines 35-38 and col. 47 lines 57-61 and col. 2 lines 15-32); presenting one of said forms to a user (Iliff; col. 12, lines 35-38 and col. 47 lines 57-61 and col. 2 lines 15-32); receiving response data from said user (Iliff; col. 12, lines 35-38 and col. 47 lines 57-61 and col. 2 lines 15-32); and in dependence on said response data and said form linking condition (Iliff; col. 12, lines 35-38 and col. 47 lines 57-61 and col. 2 lines 15-32), determining a second form to present to said user (Iliff; col. 12, lines 35-38 and col. 47 lines 57-61 and col. 2 lines 15-32).

[i] Although Iliff indicates that his method utilizes forms or screen displays to present questions and data to the user (Iliff; col. 12, lines 35-38 and col. 47, lines 57-65), Iliff fails to specifically teach the use of forms in each instance of data/question presentation to the user.

[ii] It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply Iliff's broad use of forms or screen displays for presenting data to users to Iliff's gathering of patient responses to layers of questions ultimately leading to a diagnosis (Iliff; col. 2, lines 15-32 and Abstract). The motivation would have been to arrange diseases, symptoms and questions into a set of related disease, symptoms, and question structures, such as objects or



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lists in such a way that the structures can be processed to generate a dialog with the patient (Iliff; col. 1, lines 66-67 and col. 2, lines 1-4)

[B] As per claim 25, A computer-implemented method for obtaining clinical data, comprising: obtaining a first form comprising at least one medical question from a database (Iliff; col. 2, lines 15-32, col. 12, lines 35-38); presenting said first form to a user (Iliff; col. 2, lines 21-23, col. 12, lines 35-38); receiving response data from said user (Iliff; col. 2, lines 27-29); obtaining a second form comprising a plurality of potential medical questions and at least one question assembly condition from said database (Iliff; col. 2, lines 27-29, col. 12, lines 35-38); and in dependence on said response data and said question assembly condition, selecting included questions from among said plurality of potential medical questions for inclusion in said second form (Iliff; col. 2, lines 27-29, col. 12, lines 35-38).

[C] As per claim 26, Iliff discloses further comprising obtaining at least one form linking condition from said database, and selecting said second form in dependence on said response data and said form linking condition (Iliff; col. 2, lines 15-32).

[D] As per claim 27, Iliff discloses presenting at least one of said included questions to said user (Iliff; col. 2, lines 15-32); and receiving second response data from said user (Iliff; col. 2, lines 15-32).

[E] As per claim 28, Iliff discloses obtaining at least one question linking condition from said

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database (Iliff; col. 2, lines 15-32); and in dependence on said second response data and said question linking condition (Iliff; col. 2, lines 15-32), determining additional of said included questions to present to said user (Iliff; col. 2, lines 15-32).

[i] Regarding claims 25-28, the obviousness and motivation as discussed with regard to claim 24 above are applicable to claims 25-28 and are herein incorporated by reference.

[6] Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haessler et al in view of Benigno et al., (United States Patent #6,230,142).

[A] As per claim 6, while Haessler et al., teaches conjunctions of higher-level question responses and lower-level question responses (Haessler et al.; col. 4, lines 15-31), Haessler et al., fails to teach the association of responses representing medical pathways associated with predetermined medical conditions.

[i] However, Benigno et al., teaches the gathering of patient data and question responses to represent or indicate medical pathways associated with predetermined medical conditions (Benigno et al.; col. 7, lines 50-67)

[ii] It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Haessler et al., with those of Benigno et al. The motivation to combine would have been to determine a questionnaire format that allows for the

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close tracking of a patient's condition and provides the clinical pathway for the patient (Benigno et al.; col. 7, lines 52-57).

[B] As per claim 7, Haessler et al., does not teach implementing the method in a distributed computer system.

[i] However, Benigno et al., teaches said method is performed in a distributed computer system (Benigno et al.; col. 8, lines 23-35), said database is stored in a server computer (Benigno et al.; col. 8, lines 34-45), said response data are received at a client computer (Benigno et al.; col. 8, lines 23-45), and said method further comprises transmitting said medical questions from said server computer to said client computer (Benigno et al.; col. 8, lines 27-60).

[ii] It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Haessler et al., with those of Benigno et al. The motivation to combine would have been to provide a data storage and manipulation system whereby clinical data is collected for patients and stored in appropriate databases in a client/server system such that multiple clients such as doctors, hospitals, nurses, insurance companies, and other healthcare providers can access a central repository of relevant clinical treatment information (Benigno et al.; col. 5, lines 26-33). Further motivation would have been to provide a computerized interface between the skilled nurse/caregiver, the patient, and the physician (Benigno et al.; col. 6, lines 45-48)

[C] As per claim 8, Benigno et al. discloses said determining step is performed by said client computer (Benigno et al.; col. 8, lines 23-60).

[D] As per claim 9, Benigno et al. discloses the determining step is performed by said server computer (Benigno et al.; col. 8, lines 23-60), and wherein said method further comprises transmitting said response data from said client computer to said server computer (Benigno et al.; col. 8, lines 23-60).

[i] Regarding claims 8 and 9, the obviousness and motivation to combine as discussed with regard to claim 7 above are applicable to claims 8 and 9 and are herein incorporated by reference.

[7] Claims 10-13 and, 19 rejected under 35 U.S.C. 103(a) as being unpatentable over Haessler et al., in view of Iliff.

[A] As per claim 10, although Haessler et al., teaches a database storing questions, Haessler et al., fails to disclose storing patient responses in the database.

[i] However, Iliff teaches storing said response data in a clinical database (Iliff; col. 47, lines 57-67).

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[ii] It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Haessler et al., with those of Iliff. The motivation to combine would have been to ask a patient disease related questions, and encode patient responses (Iliff; Abstract) such that future diagnostics could be enhanced by the ability to compare future patients to patient data stored or encoded in the system (Iliff; col. 7, lines 59-67 and col. 8, lines 1-10).

[B] As per claim 11, Iliff teaches storing clinical data from additional users in said clinical database (Iliff; Abstract and col. 47, lines 57-67).

[C] As per claim 12, Haessler et al. teaches further comprising, at a later time, repeating said obtaining, presenting, receiving, and determining steps to obtain later-time response data (Haessler et al.; col. 4, lines 40-44). Haessler et al., does not teach storing said later-time response data in said clinical database.

[i] However, Iliff teaches storing response data in said clinical database (Iliff; col. 7, lines 59-67, col. 8 lines 1-10 and Abstract).

[D] As per claim 13, Iliff teaches storing laboratory data in said clinical database (Iliff; col. 7, lines 59-67, col. 8, lines 1-10, and col. 10, lines 10-17).

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[E] As per claim 19, Iliff teaches assigning a weight to said response data, wherein said determining step is performed in further dependence on said weight (Iliff; Abstract and col. 24, lines 23-32 and col. 2, lines 15-32).

[i] Regarding claim 11-13, and 19, the obviousness and motivation to combine as discussed with regard to claim 10 above are applicable to claims 11-13 and are herein incorporated by reference.

[8] Claims 14-18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haessler et al., in view of Cairnes (United States Patent # 6,139,494).

[A] As per claim 14, although Haessler et al. teaches generating patient responses to questions concerning disease specific symptoms (Haessler et al.; col. 4, lines 25-31), Haessler fails to teach the comparison of patient data or responses to stored conditions or a threshold that would indicate the need for an alert.

[i] However, Cairnes teaches further comprising obtaining clinical alert conditions from said database, and comparing said response data with said clinical alert conditions (Cairnes; Abstract and Fig. 1 and col. 11, lines 24-33).

[ii] It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Haessler et al., with those of Cairnes. Such

combination would have resulted in a system capable of presenting questions to a patient, recording patient answers, and selecting subsequent questions in accordance with the answers given to previous questions (Haessler et al.; col. 1, lines 18-23). Further such combination would have provided the ability to utilize patient responses to queries to compare the clinical state of the patient to predefined medical parameters and notify a Personal Health Advisor when data exceeds the bounds of the predefined parameters (Cairnes; Abstract and col. 11, lines 24-33). The motivation to combine would have been to provide for effective sign and symptom surveillance, medications management, adherence monitoring and support, and timely responsiveness to changing conditions (Cairnes; col. 1, lines 57-64).

[B] As per claim 15, Cairnes teaches presenting a clinical alert to said user in dependence on said comparison (Cairnes; Abstract and col. 11, lines 24-33).

[C] As per claim 16, Cairnes teaches presenting a clinical alert to a designated person in dependence on said comparison (Cairnes; Abstract and col. 12, lines 13-40).

[D] As per claim 17, Cairnes teaches contacting a designated person in dependence on said comparison (Cairnes; Abstract)

[E] As per claim 18, Cairnes teaches presenting disease-specific questions to said user in dependence on said comparison (Cairnes; col. 11, lines 24-33, col. 12, lines 13-19 and col. 13, lines 34-51).

[F] As per claim 21, Cairnes teaches wherein said response data are received via a medical instrument (Cairnes; col. 2, lines 65-67, col. 3, lines 1-15).

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

(1) Consentino et al., United States Patent #6,290,646, Apparatus and Method for Monitoring and Communicating Wellness of Ambulatory Patients Parameters.

Description: In United States Patent Number 6,290,646, Consentino et al., discloses a monitoring device that incorporates transducing devices for converting the desired measured parameters into electrical signals capable of being processed by a local computer or microprocessor system. The device interacts with the ambulatory patient and then, via a modem or other electronic communication device, transmits the measured parameters to a computer located at a remote site. At the remote location, the various indicia of the ambulatory patient's condition are monitored and analyzed by the medical professional caregiver. To provide the ambulatory patient with an added level of convenience and ease of use, such monitoring device is contained in a single integrated package.

(2) Ahmed, United States Patent Application Publication #2002/0107824, System and Method of Decision Making.

Description: In United States Patent Application Publication Number 2002/0107824, Ahmed discloses a system and method that employs information systems theories and expert systems theories to provide a process, apparatus and method for decision making, based on emulation of the human decision-making process using expert-generated primary bias values, wherein a primary bias value associates a particular alternative possibility of a possibility set with a particular query, and reflects the expert's conception of the relative degree of predictive value of the query for the particular alternative relative to other alternatives in the possibility set. In particular embodiments, the present invention provides a process, apparatus and method for providing a medical diagnosis or medical self-assessment.



(3) Kehr et al., United States Patent #6,085,752, Method and Apparatus and Operating System for Managing the Administration of Medication and Medical Treatment Regimens.

Description: In United States Patent Number 6,085,752, Kehr et al., discloses a medical monitoring device, operating system, and method for managing administration of medical treatment regimens for treating a patient's medical conditions. The device stores medication schedule data, treatment data, patient query data, and patient response data. The device includes a controller for controlling modes of operation of the device, controlling access of the memory, controlling display of the treatment data and the patient query data on a display, receiving and processing patient response data, tracking timing, and providing scheduled medication alarm signals. The device further includes dedicated keys interfaced with the controller. Each dedicated key is associated with one of the medical treatment regimens, and initiates the display of treatment messages relating to the associated medical treatment regimen. Successive actuation of each dedicated key initiates the display of further treatment messages relating to the associated medical treatment regimen. The device further includes soft function keys interfaced with the controller. The soft function keys signal the controller, commanding it to execute different modes of operation of the medical monitoring device. The device provides scheduled medication alarm signals that alert the user concerning prescribed medications due to be taken.

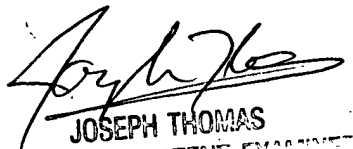
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert D. Rines whose telephone number is 571-272-5585. The examiner can normally be reached on 8:30am - 5:00pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RDR

  
JOSEPH THOMAS  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER

